



March 25th, 2011

Joan McClure, MS
Senior Vice President, Clinical Information and Publications
National Comprehensive Cancer Center
275 Commerce Dr, Suite 300
Fort Washington, PA 19034

Dear Ms. McClure,

On behalf of Bristol-Myers Squibb Co., I respectfully request the *NCCN Melanoma Panel* review the enclosed information for inclusion of Yervoy[™] (ipilimumab) on the NCCN Melanoma Treatment Guidelines for the treatment of advanced or metastatic melanoma.

Specific Changes Requested:

- In section ME-E, we respectfully request that Yervoy[™] be added as systemic therapy for patients with unresectable or metastatic melanoma. (NCCN Category 1)

FDA Clearance:

- The FDA approved Yervoy[™] (ipilimumab) for treatment of unresectable and metastatic melanoma on March 25th, 2011.

Rationale:

- In support of the requested change, FDA approval was based on a Phase III, randomized (3:1:1), double-blind, placebo-controlled, multicenter trial involving 676 subjects with previously treated unresectable stage III or IV melanoma which demonstrated a 34% reduction in risk of death in the ipilimumab alone arm compared with the gp100 control arm [median overall survival with ipilimumab alone was 10.1 months compared with 6.4 months in the control arm, gp100 peptide vaccine alone (the hazard ratio for death in comparison of ipilimumab alone with gp100 alone was 0.66; {CI: 0.51, 0.87} P=0.003)].



To assist the committee with their review, I have included the following resources:

1. Yervoy[™] (ipilimumab) prescribing information. Bristol-Myers Squibb Co.
2. Hodi FS et al. Improved survival with ipilimumab in patients with metastatic melanoma. *N Engl J Med*. 2010; Aug 19;363(8):711-23.

We acknowledge the contributions of NCCN panel members who are also co-authors or co-contributors of this publication.

Thank you for considering this request. Below is my contact information should you need to contact me for additional information.

Sincerely,

A handwritten signature in black ink, appearing to read "John Tsai", written over a large, faint, stylized outline of a triangle.

John Tsai, MD
Vice-President, Head of US Medical
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Date of request: March 25th, 2011
NCCN Guidelines Panel: Melanoma